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## **Self-expandable stents for benign esophageal leakages and perforations: long-term single-center experience**

Gubler, Christoph ; Bauerfeind, Peter

**Abstract:** **OBJECTIVE:** To date, there is no standardized treatment for esophageal perforations and leakages caused by underlying benign diseases, and it is still debated whether a conservative, endoscopic treatment or a surgical approach is preferable. However, some cases series have successfully demonstrated the feasibility of a temporary placement of self-expanding stents. **DESIGN:** All patients with benign leakages of the esophagus or gastroesophageal junction or fistulas at gastroesophageal anastomosis were collected during the past 12 years and analyzed retrospectively. The patients treated with endoscopic stenting were analyzed for sustained success, complications, time to stenting, lesion size, number of stents used, need for percutaneous drainage. **RESULTS:** Eighty-five of eight-eight patients were included in this analysis. Three patients were conservatively managed only. The success rate of stent treatment with an average of 1.3 stents was 79%. Success was highest (94%, n = 30 of 32, no complications or mortality) in iatrogenic lesions that were immediately diagnosed and treated. Spontaneous lesions, including lesions due to Boerhaave's syndrome, were healed in 73% and anastomotic leakages were closed in 71%. Fistula had a lower success rate of 43%. Use of multiple stents sequentially placed was necessary in 23% of the cases. Percutaneous drainage was necessary in 25% of all cases. **CONCLUSION:** Temporary stent placement for benign leakages of the esophagus is safe and seems to improve treatment success. Adjacent fluid collections should be drained percutaneously.

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Title Page

**Self-expandable stents for benign esophageal leakages and perforations: long term single center experience**

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Short title: Stenting for esophageal leakages

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## Abstract

Objective: To date, there is no standardized treatment for esophageal perforations and leakages caused by underlying benign diseases, and it is still debated whether a conservative, endoscopic treatment or a surgical approach is preferable. However, some cases series have successfully demonstrated the feasibility of a temporary placement of self-expanding stents.

Design: All patients with benign leakages of the esophagus or gastroesophageal junction or fistulas at gastroesophageal anastomosis were collected during the last 12 years and analysed retrospectively. The patients treated with endoscopic stenting were analysed for sustained success, complications, time to stenting, lesion size, number of stents used, need for percutaneous drainage.

Results: 85 of 88 patients were included in this analysis. Three patients were conservatively managed only. The success rate of stent treatment with an average of 1.3 stents was 79%. Success was highest (94%, n=30 of 32, no complications or mortality) in iatrogenic lesions that were immediately diagnosed and treated. Spontaneous lesions, including lesions due to Boerhaave's syndrome, were healed in 73% and anastomotic leakages were closed in 71%. Fistula had a lower success rate of 43%. Use of multiple stents sequentially placed was necessary in 23% of the cases. Percutaneous drainage was necessary in 25% of all cases.

Conclusion: Temporary stent placement for benign leakages of the esophagus is safe and seems to improve treatment success. Adjacent fluid collections should be drained percutaneously.

## Key Words (MeSH terms)

Anastomosis- leakage- esophageal perforation- esophagus- stent

## Introduction

Transmural injury of the esophageal wall or leakage at anastomotic sites after esophagogastric or bariatric surgery always leads to a life-threatening situation with high morbidity and mortality [1], [2]. The outcome is significantly influenced by the time delay between the lesion and its diagnosis [3], its location in the gastrointestinal (GI) tract [4] and its etiology.

It is still under debate whether an endoscopic or surgical approach is preferable. Reported mortality rates are still high for both approaches (30% and higher) [5], although more recent studies suggest lower mortality rates of 10% [6]. The use of covered/partially covered self-expanding metal or plastic stents (SEMS, SEPS) is clinically successful in up to 85% [7] [8], but complications such as stent migration or tissue overgrowth are of concern. To answer the

question which option is best,

-we report our experience with temporary stenting for benign esophageal leakages over the last 12 years at our tertiary referral centre.

## Methods

All data of patients with esophageal perforations or leakages at the University Hospital of Zurich have been prospectively recorded since January 1999. For this paper, esophageal stent insertions in these patients between January 1999 and December 2011 were retrospectively analyzed. Besides the overall outcome, we focussed our analysis on stent model, technical aspects, exchanging interval, complications and the need of additional percutaneous drainages. Stent insertions to treat malignant stenoses and perforations as well as fistulas resulting from active malignant diseases were excluded. On the other hand, cases of stent insertion in patients after potentially curative surgery with R0-Resection of cancers of the esophagus or stomach were included.

Diagnosis of perforation was done by means of one of three modalities: contrast medium swallow, oral contrast-enhanced computed tomography, or endoscopy. In uncertain cases endoscopically instilled contrast and fluoroscopy was used to visualize small leakages. In small fistulas, ERCP cannula catheters with or without 0.035 inch guide-wire and fluoroscopy were used to proof presence of a leakage.

Every leak or perforation was initially evaluated together with the visceral surgeon. No patient was directly sent for surgery without diagnostic gastroscopy, thus precluding a treatment selection bias. Decision for stenting, to insert drainages or to perform a thoracoscopy was then made in accordance.

All stents were placed by one of four experienced endoscopists. The following stent types with lengths from 8 to 15cm and diameters of 16 to 28mm were used: Ultraflex partially covered (Boston Scientific Corp, Natick, Massachusetts, USA), Niti-S fully covered (Taewong, Korea), Hanaro partially covered (M.I.Tech, Korea) and R sch Stent fully covered (Willy R sch GmbH, Kernen, Germany). Complementary usage of Over-the-scope-Clips (OTSC) or combination of SEMS with endo-vacuum-therapy [9] was performed accordingly the particular lesion.

All endoscopies were performed under deep conscious sedation using Olympus (Olympus Medical Systems, Tokyo, Japan) endoscopy equipment. Stents were placed with fluorescence guidance over a 0.038 inch super-stiff Amplatz guidewire (Boston Scientific Corp, Natick, Massachusetts, USA). Stent deployment was then performed under direct side-by-side endoscopic visualisation. Additionally, x-ray control was used in most cases. Site correction had to be performed in some cases by using a rat-tooth forceps to grasp the proximal end of the stent. Follow-up diagnostic modalities were either contrast medium swallow, computed tomography or, in some cases, mere clinical judgement. We have chosen a 2 week interval based on our initial experience.

Stents were extracted by pulling at the proximal end with a rat-tooth forceps. In rare cases, stents had to be inverted for extraction or a double working channel endoscope had to be used.

The following data were collected: location and size of the perforation in the esophagus, time between presumed injury and stenting, number of stents and time of stent in place, percutaneous drainages, success of stent treatment and stent-associated complications and mortality. Data were analysed in 4 groups based on the etiology of the perforation: anastomotic insufficiency (after esophagectomy, bariatric surgery), iatrogenic perforation (diagnostic endoscopy, trans-esophageal echocardiography (TEE), mucosectomy, dilatation), spontaneous lesions including Boerhaave's syndrome and all different fistulas originating from the esophagus.

Dysphagia scores during stenting were not collected. However, the initial 20 patients were asked about dysphagia in the 3 month follow-up after removal of the stent.

The primary endpoint was treatment success per stent and per patient. Stenting success was defined as complete and persistent closure of leakage or perforation for at least 4 weeks after removal without evidence of adjacent abscesses or fluid collections. rDrainage tubes had to be removed as well.

Statistical analysis was performed with IBM® SPSS® Statistics Version 20 (IBM corporation, Armonk, NY). Treatment success served as the dependent variable, stent location and indication were independent variables. Gender and age served as covariates wherever appropriate. For statistical comparisons between groups,  $\chi^2$  tests, logistic regression and t-tests were used.

## Results

A total of 85 patients (52 men, 33 women, mean age 58.8 years, range 27 – 82 years) were included. 3 additional patients were treated strictly conservatively and not included in this series. 113 SEMS were inserted in these patients, resulting in an average of 1.3 SEMS per patient with a range of 1 – 4. Most patients received 1 stent (66/85; 77%); 2, 3 and 4 SEMS were placed in 13%, 8% and 2% of patients, respectively. The total number of successful stents (1.32 stents median) and the unsuccessful serial stents (1.37 stents median) were comparable.

Pictures 1-3 demonstrate the closure of a large perforation in the distal esophagus, which was diagnosed with a delay, but nevertheless treated successfully with 3 consecutive stents left in place for two weeks.

Average lesion size was 1.4cm in diameter with a range from 0.1 to 5cm largest. Lesion size was not correlated to a particular etiology of the esophageal lesion. Subgroups of indications for stent placement and success rates are shown in table 1. Overall, the closure of lesions of all types and locations was successful in 79% of patients (67/85). However, success varied significantly between the 4 indication groups ( $P = 0.013$ ,  $\chi^2 = 10.8$ ,  $df = 3$ ). This significant difference is mainly due to the low success rate in the treatment of fistulas (43%;  $P = 0.003$  for the comparison of success rate in treatment of fistulas vs. success rate in the treatment of the remaining three indication groups). When fistulas were removed from the calculation, the difference in success rates between indication groups was not significant ( $P = 0.35$ ,  $\chi^2 = 2.1$ ,  $df = 2$ ). Closure of lesions was most successful in the iatrogenic group (94%; 30/32 patients) in which only the subgroup of transesophageal echocardiography showed a result below 100%. Sustained closure of fistulas was achieved in 43% of patients (3/7), but only esophago-tracheal fistulas could be closed by stenting; closure of fistulas to the pericardium, the aorta, the cutis and the pleura was not successful with stenting alone.

Stents were inserted immediately (same procedure or same day) in 19/85 patients (22%) after the perforation diagnosis. Time lag between diagnosis of perforation and stent implantation was 17 days (mean, range 1- 480) in all other cases. Most of the anastomotic leakages and fistula belong to them. Immediate stent insertion upon endoscopic diagnosis of the perforation led to a 100% success score; delayed stent placement was less successful (71%).

25 (29.5%) lesions were located in the proximal esophagus, defined as 20 cm from the teeth and higher. 19 (22.5%) were in the middle third (20-30cm from the teeth) and 41 (48%) in the distal esophagus below 30cm from the teeth. Iatrogenic lesions and fistulas occurred in all thirds of the esophagus evenly distributed. Spontaneous perforations and leakages after surgery were located



in the middle and distal third. Success was related to the location in the esophagus. The success rate was highest in the proximal (88%, 22/25 patients) and distal (83%, 34/41 patients) part of the esophagus compared to lower success in the middle part of the esophagus (58%, 11/19 patients) ( $P = 0.04$ ,  $\chi^2 = 6.4$ ,  $df = 2$ ). Excluding the fistula group had no influence on these results in terms of anatomic site.

21/85 (25%) patients needed percutaneous or thoracoscopic drainage of peri-esophageal fluid collections after stenting, whereas 26/85 (30%) had a drainage already in place at the time of the diagnosis of perforation. In two cases an OTSC was used. In one patient an esophago-pericardial fistula was closed successfully following an ineffective stenting period of 2 weeks [10]. After 2 subsequent stents one OTSC was applied in addition with success in another patient. Two more patients had an additional vacuum-therapy during the first (of two) respective second (of three) stent implantations with favourable outcome.

Ultraflex SEMS with an outer diameter of 23 and 28mm, a length ranging between 9 and 12cm and 15mm long uncovered ends at both sides were used in the majority of insertions (72/113; 64%). Some patients (28/113; 25%) received a fully covered Niti-S model with body-shaft diameters between 18 and 30mm and lengths ranging between 8 and 15cm.

Successful placement proven by visual control was achieved in all procedures. Success related to a particular stent model was calculated only for the 2 most frequently used ~~and forecited~~ SEMS (Ultraflex and Niti-S). The stent-associated closure rate was 68% (49/72) for the Ultraflex and 54% (15/28) for the Niti-S stent.

In the first 20 patients (23%), swallowing was assessed by telephone interview 3 months after removal of the stent. None of these patients suffered from dysphagia.

Stent complications were few and endoscopically manageable in all cases. Altogether 10/113 (8.85%) stents migrated distally within the gastrointestinal lumen. All except one migrated stents were removed endoscopically. Only one stent passed spontaneously through GI tract without

intervention. 7 of 10 migrated stents were replaced during the same procedure. Bolus obstruction occurred only once (0.88%).

Average stenting time was 15 days (range 1-111 days). 107 of 113 (95%) stents were removed with rat-tooth forceps, none had to be removed with the inlet technique [11]. 3 patients (3.5%) died from causes unrelated to the not removed stent.

In our cohort we had a 30 days overall mortality of 5.8%. 5 patients died within 3 weeks after stent removal due to not associated diseases (2 multi organ failure, 1 ARDS, 1 heart insufficiency and aortic dissection). 2 stents were irremovable, but these patients were still alive at the time of this publication.

There was no stent-related death within this patient collective.

## Discussion

Perforations and leakages in non-malignant circumstances in the upper GI-tract remain a clinical challenge with high morbidity, long hospital stays and a broad range of reported mortality from 0 to 31% [12]. Most of the known reports are based on small case series for the surgical [13] as well as for the conservative approach [3]. In the last decade, there has been some evidence in favour of an aggressive conservative approach with percutaneous drainage [14] and the endoscopic management using mainly SEMS. Besides meta-analyses, reviews and small case collections, only one large series [8] has been reported, and it clearly supports a primarily endoscopic approach using SEMS. Our data support this conclusion with similar success and even lower complication rates.

We did not follow those treatment algorithms suggested in the surgical literature [12] which primarily aim to repair and resect, but pursued a stenting approach. All referred patients were discussed with the surgeons and after endoscopy managed whenever possible by stent insertion. We had an overall success rate of 79% in our patients and were thus able to prevent emergency treatments or delayed surgery. Analysing the four subgroups with different indication for stenting,

we found that healing was definite for 94% of the iatrogenic lesions. All lesions resulting from dilatation, mucosectomy and rigid endoscopy healed sustainably after stenting. Lesions after TEE are typically located in the cervical esophagus [15] and are best treated by over-sewing and drainage [16]. 5 lesions (two distal, two in the thoracic part, and only one in the cervical esophagus) of this type in our sample were treated in 60% (3/5) successfully by one single stent. Whether subsequent SEMS would have closed the lesions in the remaining two patients stays unanswered. Otherwise a strictly conservative approach is nowadays not feasible.

There was also a fairly good outcome after stent placement in patients with anastomotic insufficiencies: in 71% the leakage was closed. The subgroup with anastomotic insufficiency after bariatric surgery consisted of 8 patients with a similar success rate of 73%. In two patients, 2 OTSC were needed in between SEMS insertions; they fell off after 2 weeks. Our cases underline that post-bariatric insufficiencies are best treated by sequential endoscopic interventions [17].

With respect to spontaneous lesions we could show a similar success rate as for iatrogenic perforations, although the subgroups are doubtless very small. Nevertheless the quite high success rate of 71% in sealing Boerhaave's syndrome is to stress out. Fistulas are not surprisingly challenging to treat. Our low lasting closure success underlines this known fact, although fistulas into the trachea may be closed by SEMS treatment.

Location of the lesions in relation to the esophageal body seems to be an important factor for success. Best results were achieved for lesions in the proximal part, followed by lesions in the distal part. This is most likely due to the fact, that the majority (75%) of iatrogenic lesions were located in the proximal and distal parts, which were treated with the shortest delay and without established systemic infection.

Immediately observed perforations had an excellent outcome. Not having inflamed tissue or surrounding fluid collections, which become infected, may be an explanation for this observation.

On the other hand, drainage of fluid collections does not seem to be an absolute condition for success. Instead, the existence of vital covering tissue outside the GI lumen is probably more

crucial for success. Drainages may promote the development of covering tissue and thus lead to sustained sealing [14].

Stenting is always part of a comprehensive strategy for each individual patient. Besides technical aspects as discussed later, recurring questions concern additional endoscopic techniques and repeatability of SEMS insertion.

In 4 patients, additional endoscopic treatment was used to reach overall success. In two patients, the novel Over-the-scope-clip was subsequently used twice for 2 weeks, as described earlier [18]. In two patients, endoscopic vacuum treatment [19] for large paraesophageal cavities was used successfully.

Persistence of perforation after SEMS removal should not be stated prematurely as a treatment failure. As shown in results, a serial SEMS up to 4 times seems reasonable. Question about re-stenting is intimately connected with the durability of the stent material and suspected difficulties of SEMS removal. SEMS fractures or coating defects are not an issue, only single cases have been described so far. There is concern about difficulties in removing stents owing to tissue in-growth [20] leading to stent fracture, severe bleeding and even perforation [21]. The optimal duration of stent therapy has not been determined yet, but removal within 6 weeks [22] and the use of fully covered stents is suggested. We left our stents in place for an average of 15 days, which made re-stenting necessary in some cases. Nevertheless, 77% of patients were treated with only one stent and the average number of stents needed per perforation or leak was 1.3. This relatively short timed stent exchange interval may be the explanation, why we had seldom difficulties with stent removal. Compared to recommendations from other large series [7],[8], we advocate short stent placement times of about 2 weeks after which the stent should be removed and the lesion re-evaluated. This planned inspection of the lesion has many advantages. In case of sealed perforation any unnecessary continuation in position raises the complication rate and prolongs unpleasant food restrictions. Last but not least are stent migrations earlier detected. A second stent has to be placed immediately in case of persistence of the leak. In such cases, the

new stent's position, length and diameter can be adjusted, if needed. Recurrent stent insertions may be cost intensive at first sight, but stents left in place for extended periods of time may also produce costs and complications. In the case of tissue hyperplasia, a plastic or fully covered metallic stent-in-stent will be necessary. It is difficult to estimate the comparative costs of the two different approaches, but shorter placement times will eventually shorten hospital stays and therefore be cost-effective.

A biweekly stent placement time seems reasonable as also shown by Salminen [23].

Higher migration rates may be the price for the better removability of fully covered stents, as has been shown in esophageal malignancies [24]. A trade-off is a stent design with some uncovered sections which allow selective tissue in-growth to keep the stent in place.

Therefore, we used the Ultraflex stent in 68% of procedures and no migration event occurred.

This is in line with low migrations rates of 3% published by Leers et al using the same stent model [25]. The fully covered Niti-S was the second most frequently used stent and had a migration rate of 36% (10/28 stents). One (out of three) Hanaro stent passed spontaneously through the anorectum. Fully covered SEMS were fixated with endo-clips [26] in 3 cases, but this was unhelpful and cannot be recommended due to the fact that esophageal peristalsis may be too strong for mucosal anchoring.

Our study has some limitations. It is a single center study without comparative groups such as surgical or strictly conservative treatment. Due to the retrospective nature of the analysis of endoscopy reports, the data on lesion size and shape is not robust. A referral bias is possible, although this would not contradict our stenting strategy in critically ill patients. However, we believe that a future prospective randomized blinded trial, though wanted and preferable, will not be carried out due to the evidence for endoscopic stent placement.

In conclusion, stent placement should be the method of choice for the treatment of almost any "benign" perforating lesion in the upper GI tract, irrespective of its etiology, maturity, size and

location. Every patient should be assessed by a team composed of a gastroenterologist, visceral surgeon and the attending doctor. The most important factor for treatment success is a short time delay between the occurrence of the leakage and stent insertion. An immediate diagnosis of suspected lesions should therefore be attempted by means of endoscopy, CT scan and gastrografen swallow. A re-evaluation by stent removal and re-stenting if necessary is to be scheduled after approximately 2 weeks. Partially covered SEMS exhibit a favourable balance of low migration rate and easy removability. Cavities and infected tissue have to be drained based on individual clinical judgement.

Consecutive stenting is safe and allows closure of benign perforations in the esophagus in the majority of cases.

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Table 1: Subgroups of etiology and success rate

	Subgroup	Number	Success %
Iatrogenic		32	30/32 = 94%
	Dilatation	10	100%
	Mucosectomy	10	100%
	TEE	5	60%
	Rigid endoscopy	3	100%
	Surgery at hiatus	3	100%
	tracheotomy	1	100%
Anastomosis insufficiency		31	23/31 = 74%
	Esophagectomy	18	72%
	Sugiura procedure	1	100%
	Bariatric surgery	11	73%
	Gastrectomy	1	100%
Spontaneous		15	11/15 = 73%
	Boerhaave's syndrome	7	71%
	Foreign bodies	2	100%
	Miscellaneous Lichen ruber Severe reflux M. Crohn esophagus Penetration osteosynthesis Midesophageal diverticulum Ischemia	6	66%
Fistula		7	3/7 = 43%
	Esophago-tracheal	4	75%
	Esophago-aortal	1	0%
	Esophago-pleural	1	0%
	Esophago-cutan	1	0%
	Esophago-pericardial	1*	0%
All patients		85	66/85 = 78%

\*listed in TEE-associated lesions

### **Figure Legends**

Figure 1 Persistent perforation after removal of the first self-expanding metal stent

Figure 2 Deployment of a self-expanding partially covered stent

Figure 3 After removal of SEMS, diffuse mucosal bleeding